

OCT 22 2007

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

10/17/07

**FEE TRANSMITTAL**  
**For FY 2007**

Effective on 12/08/2004.  
Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$ 180.00)

<b>Complete if Known</b>	
Application Number	09/709,045
Filing Date	November 10, 2000
First Named Inventor	M. Ridgon Lentz
Examiner Name	Lorraine Spector
Art Unit	1647
Attorney Docket No.	LEN 102

**METHOD OF PAYMENT** (check all that apply)

Check  Credit Card  Money Order  None  Other (please identify): \_\_\_\_\_  
 Deposit Account Deposit Account Number: 50-3129 Deposit Account Name: Pabst Patent Group LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below  Charge fee(s) indicated below, except for the filing fee  
 Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17  Credit any overpayments

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

<b>Application Type</b>	<b>FILING FEES</b>		<b>SEARCH FEES</b>		<b>EXAMINATION FEES</b>		
	<b>Fee (\$)</b>	<b>Small Entity</b>	<b>Fee (\$)</b>	<b>Small Entity</b>	<b>Fee (\$)</b>	<b>Small Entity</b>	<b>Fees Paid (\$)</b>
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

**2. EXCESS CLAIM FEES**

**Fee Description**

Each claim over 20 (including Reissues)

**Small Entity**

**Fee (\$)** **Fee (\$)**

50 25

Each independent claim over 3 (including Reissues)

200 100

Multiple dependent claims

360 180

<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Multiple Dependent Claims</b>
- 20 or HP =	x	=		<b>Fee (\$)</b> <b>Fee Paid (\$)</b>

HP = highest number of total claims paid for, if greater than 20.

<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
- 3 or HP =	x	=			

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
- 100 =	/ 50 =	(round up to a whole number) x		=

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

**Fees Paid (\$)**

Other (e.g., late filing surcharge): Information Disclosure Statement

180.00

**SUBMITTED BY**

Signature		Registration No. 31,284 (Attorney/Agent)	Telephone 404-879-2151
Name (Print/Type)	Patreia L. Pabst		Date October 19, 2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/709,045
Filing Date	November 10, 2000
First Named Inventor	M. Ridgon Lentz
Art Unit	1647
Examiner Name	Lorraine Spector
Attorney Docket Number	LEN 102

### ENCLOSURES (Check all that apply)

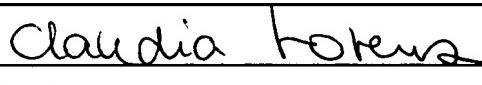
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):  <b>Eight (8) Pages PTO-Form 1449; Fifty-seven (57) References; Return Postcard Receipt</b>
Remarks		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Pabst Patent Group LLP		
Signature			
Printed name	Patrea L. Pabst		
Date	October 19, 2007	Reg. No.	31,284

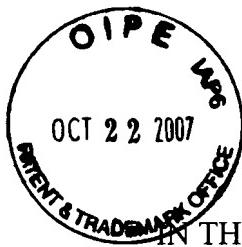
### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Claudia Lorenz	Date	October 19, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: M. Rigdon Lentz

Serial No.: 09/709,045 Art Unit: 1647

Filed: November 10, 2000 Examiner: Lorraine Spector

For: *METHOD AND SYSTEM TO REMOVE CYTOKINE INHIBITOR IN PATIENTS*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits a Supplemental Information Disclosure Statement, including eight (8) pages of Form PTO-1449, and copies of the fifty-seven (57) documents cited therein. This application is allowable and is currently in an interference at the Board of Patent Appeals and Interferences.

This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(d) after a Notice of Appeal. The Commissioner is hereby authorized to charge \$180.00, the fee set forth under 37 C.F.R. § 1.17(p), to Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-1329.

10/23/2007 AAHNADI 00000011 503129 09789845  
01 FL:1806 180.00 DA

U.S.S.N.: 09/709,045  
Filed: November 10, 2000  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

WINTER, et al. "Synthetic human antibodies and a strategy for protein engineering," *FEBS Letters*, 430:92-94(1998).

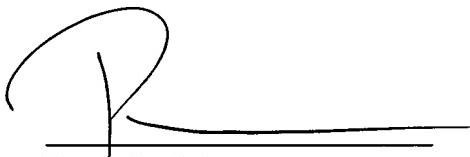
YAMAZAKI et al. Biocompatibility of plasma separator of an improved cellulose acetate hollow fiber. In: Sieberth HG (ed). *Plasma Exchange*. New York: fk Schattauer, 45-51(1980).

ZIEGLER-HEITBROCK, et al., "Tumor necrosis factor as effector molecule in monocyte-mediated cytotoxicity," *Cancer Res* 46:5947-52 (1986).

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: October 19, 2007

PABST PATENT GROUP LLP  
400 Colony Square, Suite 1200  
1201 Peachtree Street  
Atlanta, Georgia 30361  
(404) 879-2151 (Telephone)  
(404) 879-2160 (Fax)

U.S.S.N.: 09/709,045  
Filed: November 10, 2000  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

### U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,439,332	03-27-1984	Frank	507/225
4,708,713	11-24-1987	Lentz	604/5
4,863,611	09-05-1989	Bernstein	210/661
5,135,919	08-04-1992	Folkman et al.	514/56
5,147,638	09-15-1992	Esmon, et al.	424/085.8
5,290,807	03-01-1994	Folkman, et al.	514/475
5,610,279	03-11-1997	Brockhaus	530/387.3
5,629,327	05-13-1997	D'Amato	514/323
5,639,725	06-17-1997	O'Reilly, et al.	514/012
5,698,586	12-16-1997	Kishimoto, et al.	514/475
5,712,291	01-27-1998	D'Amato	514/323
5,713,491	02-03-1998	Hughes, et al.	222/129
5,716,981	02-10-1998	Hunter, et al.	514/449
5,733,876	03-31-1998	O'Reilly et al.	514/12
5,712,291	06-27-1998	D'Amato	514/323
5,808,029	09-15-1998	Brockhaus	536/23.5
5,817,522	10-06-1998	Goodman, et al.	436/165
6,133,431	10-17-2000	Yusada	530/413
6,379,708	04-30-2002	Howell, et al.	424/529

### U.S. Patent Applications

<u>Number</u>	<u>Publication Date</u>	<u>Inventor</u>	<u>Class/Subclass</u>
2005-0244371 A1	06-14-2005	Lentz	424/085
2005-0265996 A1	12-01-2005	Lentz	424/133
09/709,045	11-10-2000	Lentz	424/0085
09/699,003	10-26-2000	Lentz	604/008

### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 99/61085 A	12-02-1999	Lentz	PCT

## Publications

AGISHI, Anion-blood contact (ABC reaction) in patients treated by LDL apheresis with dextran sulfate-cellulose column while receiving ACE inhibitors (letter). *JAMA*; 271:195-6(1994).

ANDREWS, et al., "Characterization of the receptor for tumor necrosis factor (TNF) and lymphotoxin LT) on human T lymphocytes: TNF and LT differ in their receptor binding properties and the induction of MHC class I proteins on a human CD4+ T cell hybridoma," *J Immunol* 144:2582-2591 (1990).

BANYAI et al., "Therapeutic efficiency of lipoprotein(a) reduction by low-density lipoprotein immunoapheresis," *Metabolism* 47(9):1058-1064 (1998).

BONAVIDA, et al., (eds), *Tumor Necrosis Factor/Cachecin and Related Cytokines*. Int. Conf. Tumor Necrosis Factor and Related Cytotoxins, Heidelberg, 1987, pp. 7-19 (Karger, Basel1988).

CHEN, et al., "Soluble TNF- $\alpha$  Receptors are constitutively shed and downregulate adhesion molecule expression in malignant gliomas," *J. Neuropathol. Exp. Neurol.* 56(5):541-550 (1997).

CLACKSON, et al., "Making of antibody fragments using phage display libraries," *Nature* 352: 624-688 (1991).

COLMAN, et al., Hemostasis and Thrombosis: Basic Principles and Clinical Practice 2nd. Edition (Colman, et al., eds.) pp. 242-267 J.B. Lippincott: Philadelphia, PA, 1987.

CYTOLOGIC, "Unleash Immunotherapy," CytoLogic non CDA info.doc , pp.1-10 (April 27, 2006).

DAUGHERTY, et al., "Polymerase chain reaction facilitates the cloning, CDR-grafting, and rapid expression of a murine monoclonal antibody directed against the CD18 component of leukocyte integrins," *Nucl. Acids Res.* 19: 2471-2476 (1991).

EY, et al., "Isolation of pure IgG<sub>1</sub>, IgG<sub>2a</sub>, and IgG<sub>2b</sub> immunoglobins from mouse serum using protein A-Sepharose," *Immunochemistry* 15:429-436 (1978).

FEINMAN, et al., "Tumor necrosis factor is an important mediator of tumor cell killing by human monocytes," *J Immunol* 138:635 (1987).

U.S.S.N.: 09/709,045  
Filed: November 10, 2000  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

GATANAGA, et al., "Purification and characterization of an inhibitor (soluble tumor necrosis factor receptor) for tumor necrosis factor and lymphotoxin obtained from the serum ultrafiltrates of human cancer patients," *Proceedings of the National Academy of the USA* 87(22):8781-8784 (1990).

GATANAGA, et al., "Identification of TNF-LT blocking factor(s) in the serum and ultrafiltrates of human cancer patients," *Lymphokine Res* 9:225-9 (1990).

GUYTON and HALL, Textbook of Medical Physiology 9<sup>th</sup> ed. Pp. 299

HARANAKA, et al, "Cytotoxic activity of tumor necrosis factor (TNF) on human cancer cells in vitro," *Jpn J Exp Med* 51:191 (1981).

HARLOW et al., *Antibodies, A Laboratory Manual*, Chapter 13, "Immunoaffinity Purification," pp. 511-552, 1988

Hemostasis and Thrombosis: Basic Principles and Clinical Practice 2nd Ed., Colman, R.W., et al., p. 263 (J.B.Lippincott, Philadelphia, PA 1987),

HONG et al., "Intercellular adhesion molecule-1 expression induced by interleukin (IL)-1 beta or an IL-1 beta fragment is blocked by an IL-1 receptor antagonist and a soluble IL-1 receptor," *Journal of Neuroimmunology*, 44(2):163-170 (1993).

HOWARD, et al., Vaccinia virus homologues of the Shope fibroma virus inverted terminal repeat proteins and a discontinuous ORF related to the tumor necrosis factor receptor family," *Virology* 180(2):633-47 (1991).

IBM Technical Disclosure Bulletin, Vol 19, No 3. August 1976 pp. 765-768

JABLONSKA & PEITRUSKA, "Release of soluble tumor necrosis factor receptors from polymorphonuclear cells of breast cancer patients," *Arch Immunol Ther Exp (Warsz)*. 45(5-6):449-53 (1997).

JANEWAY, et al. Immunobiology: The Immune System in Health and Disease , 4<sup>th</sup> Ed. Pp.102

KABAT, et al., Sequences of Proteins of Immunological Interest 4<sup>th</sup> Ed. (U.S. Dept. Health and Human Services, Bethesda, MD, 1987).

KAMINSKA, et al. „Clinical significance of serum cytokine measurements in untreated colorectal cancer patients: soluble tumor necrosis factor receptor type I--an independent prognostic factor," *Tumour Biol.* 26(4):186-94(2005).

U.S.S.N.: 09/709,045  
Filed: November 10, 2000  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

KAMINSKA, et al "Pretreatment serum levels of cytokines and cytokine receptors in patients with non-small cell lung cancer, and correlations with clinicopathological features and prognosis. M-CSF - an independent prognostic factor," *Oncology* 70(2):115-25(2006).

KOJIMA, et al. "Effect of nafamostat mesilate on bradykinin generation during lowdensity lipoprotein apheresis using a dextran sulfate cellulose column," *ASAIO Trans* 37: 644-8(1991).

LANGKOPF, et al., "Soluble tumor necrosis factor receptors as prognostic factors in cancer patients," *Lancet* 344:57-58 (1994).

LENTZ, "Continuous whole blood UltraPheresis procedure in patients with metastatic cancer," *Journal of Biological Response Modifiers* 8(5):511-527 (1989).

LENTZ, "The role of therapeutic apheresis in the treatment of cancer: a review," *Therapeutic Apheresis* 3(1):40-49 (1999).

MARUYAMA, et al. "Evidence for aberrant activation of the interleukin-2 autocrine loop by HTLV-1-encoded p40x and T3/Ti complex triggering," *Cell.* 48(2):343-350(1987).

MATHIAS, et al., "Activation of the Sphingomyelin signaling pathway intact EL4 cells and in a cell-free system by IL-1b," *Science* 259:519-522 (1993).

MATSCHINER, et al., Current Advances in Vitamin K Research, pp. 135-140, John W. Suttie, ed. (Elsevier Science Publishing Co., Inc. 1988)

MITTEREGGER, et al., "In vitro cell culture systems as the basis for an extracorporeal blood purification strategy in multiorgan failure treatment", *Ther Apher.*, 3(3):257-63 (1999).

NATIONAL CANCER INSTITUTE, "Biological Therapies for Cancer: Questions and Answers," National Cancer Institute FactSheet (08-16-2004).

OLD, Antitumor activity of microbial products and tumor necrosis factor, and Bonavida B, et al., (eds): *Tumor Necrosis Factor/Cachecin and Related Cytokines*, Basell, Karger, p7 (1988).

PALASZYNSKI," Synthetic C-terminal peptide of IL-1 functions as a binding domain as well as an antagonist for the IL-1 receptor," *Biochemical and Biophysical Research Communications*, 147(1):204-211(1987).

PENNICA et al., "Characterization of a recombinant extracellular domain of the type 1 tumor necrosis factor receptor: evidence for tumor necrosis factor-alpha induced receptor aggregationm," *Biochemistry* 31(4):1134-1141(1992).

U.S.S.N.: 09/709,045  
Filed: November 10, 2000  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

PENNICA et al., "Biochemical characterization of the extracellular domain of the 75-kilodalton tumor necrosis factor receptor," *Biochemistry* 32(12): 3131-3138(1993).

PHILIP & EPSTEIN, "Tumor necrosis factor as immunomodulator and mediator of monocyte cytotoxicity induced by itself, Gamma-interferon and Interleukin-1," *Nature* 323(6083):86-87 (1986).

Product description: catalog number AB-225-PB catalog of R&D Systems. (1994).

Product description: catalog number AB-226-PB catalog of R&D Systems (1994).

Product description: catalog numbers FAB225F catalog of R&D Systems (1998).

Product description: catalog numbers MAB225 catalog of R&D Systems (1998),.

Product description: catalog numbers AF-425-PB catalog of R&D Systems (1998).

Product description: of antibody AHR3912. Biosource catalog

SELINSKY, et al., "Multifaceted inhibition of anti-tumor immune mechanisms by soluble tumour necrosis factor receptor type-1," *Immunology* 94(1):88-93 (1998).

SHIBATA, et al., "Changes of cell-mediated immunity with an advance of cancer-relation to the th1/th2 balance and inhibitors of th1 cytokines", *Biotherapy*, 12(5):715-17 (1998).

SIDHU AND BOLLON, "Tumor necrosis factor activities and cancer therapy - A perspective" *Pharmacol. Ther.* 57:79-128 (1993).

TETTA, et al., "Continuous plasma filtration coupled with sorbents," *Kidney International* 53(66):S186-S189 (1998).

URBAN, et al., "Tumor necrosis factor: A potent effector molecule for tumor cell killing by activated macrophages," *Proc Natl Acad Sce USA* 83:5233-37 (1986).

VAN ZEE, et al., "Tumor necrosis factor soluble receptors circulate during experimental and clinical inflammation and can protect against excessive tumor necrosis factor alpha *in vitro* and *in vivo*" *PNAS* 89:4845-4849 (1992).

VERMA et al., "Antibody engineering: comparison of bacterial, yeast, insect and mammalian expression systems," *Journal of Immunological Methods*, 216(1-2):165-181(1998).

WARZOWA, et al. "Tumor necrosis factor ligand-receptor system can predict treatment outcome in lymphoma patients," *J Clin Oncol.* 15(2):499-508(1997).